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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,118	10/02/2003	Kohei Nishikawa	087147-0489	6031

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,118	NISHIKAWA ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10-02-03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

An Information Disclosure Statement filed October 2, 2003 is acknowledged and has been reviewed. Claims 1-19 are presented and represent all of the claims under consideration.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1-13 of copending Application No. 6,040,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to administration of compounds that are presently claimed to treat glomerulonephritis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 6,319,938. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are

drawn to administration of compounds that are presently claimed to treat glomerulonephritis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7-10 and 16-18 are rejected under 35 U.S.C. 112, both first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the invention, and for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

Applicants fail to particularly point out the definition of "substituted hydrocarbon residue" for the R^1 term, the groups "capable of forming an anion" and the "spacer having anatomic chain length of two or less" for the R^3 term. Simply providing several examples does not distinctly claim and point out the subject matter that Applicants regard as the invention. The metes and bounds of "substituted hydrocarbon residue", "a group capable of forming an anion" and the "spacer having anatomic chain length of two or less" cannot be precisely determined. Numerous compounds that lack enablement and an adequate teaching as to how to prepare them are encompassed in the language of claim 1. Undue experimentation would be required to embrace the scope of the claims. Applicants should recite those hydrocarbon residues, groups and spacers contemplated. All substituents must be defined.

Claims 1-11 and 16-19 are rejected under 35 U.S.C., first paragraph, because the specification, while being enabling for tetrazole or oxadiazole, does not provide

enablement for any optional substituent on ring A other than R^2, or, any optionally substituted 5-7-membered monocyclic heterocyclic residue having a hydrogen atom capable of leaving a proton in claim 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prepare the invention commensurate in scope with these claims. In consideration of the specificity of receptors and the plethora of functional groups encompassed in the claim language, it would not have been reasonable to expect any and all compounds encompassed within the broad definitions of the R^3 term would function in a method of treating glomerulonephritis. A more detailed written description directed to the means of preparing the compounds encompassed in the claim language and practicing methods for the prophylaxis or treatment of glomerulonephritis is required.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the prophylaxis or treatment of glomerulonephritis comprising administering a compound of instant formula I, or the formula of instant claim 19. The specification provides support for the treatment of proteinuria and albuminuria comprising administering one compound, 1-(cyclohexyloxycarbonyloxy)ethyl-2-ethoxy-1-[[2'(1H-tetrazole-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prophylaxis or treatment of glomerulonephritis.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the field of urology.

While there are conventional therapies that are well established in the art to treat glomerulonephritis, the prophylaxis of this disease state would require further disclosure

to support a contention that the use of the claimed compounds are capable of prevention.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are not broad; however, eliminating the possibility of the development of glomerulonephritis, especially when the etiology, or the predisposing factors, is unknown, is essentially impossible.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to treating proteinuria and albuminuria.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compounds would be preferred for prophylaxis or glomerulonephritis. The skilled artisan would expect the interaction of a particular drug in the prophylaxis this particular disease state to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding or any criteria for extrapolating beyond the administration of a single compound that may be useful for treatment of glomerulonephritis. No direction is provided for prophylaxis. Absent reasonable *a priori* expectations of success for preventing the disease, one skilled in the urology art would have to test extensively the

many compounds encompassed in the language of the claims under conditions that are not described in the specification. Undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Mondays to Fridays from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

July 10, 2005